UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
MIDDLE DIVISION

PATRICIA AKINS, MONIQUE BAKER, RUTH EPPERSON, CORY FLENOY, NAKITTA GAMBLE, and JAMES MCCLINTON on behalf of themselves and all other persons similarly situated, Plaintiffs, vs. IOVATE HEALTH SCIENCES USA, INC., a Delaware corporation and IOVATE HEALTH SCIENCES, INC., an Ontario, Canada corporation, Defendants.	§ § § § § § § § § § § §	Civil Action No.:_____ **CLASS ACTION** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

COMES NOW the Plaintiffs, Patricia Akins, Monique Baker, Ruth Epperson, Cory Flenoy, Nakitta Gamble, and James McClinton, on behalf of themselves and for all other persons similarly situated, and for their original Class Action Complaint against the Defendants, would allege as follows:

PRELIMINARY STATEMENT

1. Plaintiffs files this Class Action seeking damages on behalf of themselves and all others similarly situated for violations of Tennessee common and statutory law.

2. Plaintiffs and all Class Members purchased certain defective and dangerous weight loss products manufactured and/or distributed by Defendants. On May 1, 2009, the United States Food and Drug Administration issued a recall order for those certain defective and dangerous products because they posed a risk of "serious liver injuries" (See those certain FDA recall attached as Exhibit A).

3. The Defendants in this action are Iovate Health Sciences, Inc. and Iovate Health Sciences USA, Inc.

4. The Defendants are liable for damages and penalties under Tennessee law because they deceptively, fraudulently, and/or negligently induced the Plaintiffs and Class Members into purchasing their defective and dangerous products.

THE PARTIES

5. The Plaintiff Patricia Akins is a resident of Tennessee with a principal residence at 103 Whitson Court, Murfreesboro, TN 37129. The Plaintiff Monique Baker is a resident of Tennessee with a principal residence at 3209 Sennadale Lane, Nashville, TN 37207. The Plaintiff Ruth Epperson is a resident of Tennessee with a principal residence at 2208A 12th Avenue South, Nashville, TN 37204. The Plaintiff Cory Flenoy is a resident of Tennessee with a principal residence at 927 William Edmonson Street, Nashville, TN 37203. The Plaintiff Nakitta Gamble is a resident of Tennessee with a principal residence at 3209 Sennadale Lane, Nashville, TN 37207. The Plaintiff James McClinton is a resident of Tennessee with a principal residence at 263 Fox Creek Court, Manchester, TN 37355.

6. Defendant, Iovate Health Sciences, Inc. is a corporation incorporated under the laws of Ontario, Canada, with its principal place of business in 381 North Service Road West, Oakville, ON, L6M04H.

7. Defendant, Iovate Health Sciences USA, Inc. is a corporation incorporated under the laws of Delaware, with its registered agent located at c/o Capitol Corporate Services, Inc., 1111B South Governors Avenue, Dover, DE 19904.

8. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' damages.

FACTUAL BACKGROUND

9. For more than seven (7) years, Defendants have manufactured, tested, marketed and sold a series of weight loss drugs and supplements under the trade name of Hydroxycut.

10. The primary ingredients in most Hydroxycut products include garcinia cambogia, gymnema sylvestre, chromium polynicotinate, caffeine, and green tea.

11. Defendants have extensively tested their products before placing them in the stream of commerce.

12. Defendants have marketed their Hydroxycut products through print and television advertising.

13. During the past seven years, Defendants have marketed their Hydroxycut products as being created by and endorsed by doctors.

14. Television ads for Hydroxycut have featured Jon Marshall, a graduate of Midwestern University's osteopathic medical school. Hydroxycut has also been endorsed by its

formulator, Marvin Heuer, Associate Clinical Professor in the Department of Family Medicine and Community Health at the University of Florida, and Chief Scientific Officer of Iovate Health Sciences, the manufacturer and Defendant in this class action lawsuit.

15. In 2003, the State of Missouri filed suit against Defendants for engaging in misleading advertising. While that case settled out of court, Defendants have not substantially changed their advertising of Hydroxycut products since 2003.

16. Prior to May 1, 2009, Defendants knew or reasonably should have known of the adverse health consequences associated with their Hydroxycut products as a result of many reasons including, but not limited to, those certain studies and reports published in scientific journals.

17. Two cases of acute liver injury directly associated with the use of Hydroxycut were reported in the March 15, 2005 issue of the Annals of Internal Medicine.

18. In October, 2007, the American Journal of Gastroenterology reported that a soldier deployed to Iraq suffered an acute liver injury from consuming Hydroxycut.

19. On December 7, 2008, a report in World Journal of Gastroenterology warned that:

> "Dietary supplements represent an increasingly common source of drug-induced liver injury. Hydroxycut is a popular weight loss supplement which has previously been linked to hepatotoxicity, although the individual chemical components underlying liver injury remain poorly understood. We report two cases of acute hepatitis in the setting of Hydroxycut exposure and describe possible mechanisms of liver injury."

20. In the February, 2009 issue of Digestive Diseases and Sciences, a case report examined the links between Hydroxycut products and hepatotoxicity.

21. On April 14, 2009, a study published in World Journal of Gastroenterology stated that:

> "a case series of two patients with hepatotoxicity associated with the weight-loss supplement Hydroxycut, so named because it contains potentially hepatoxic hydroxycitric acid derived from the tropical fruit Garcinia cambogia. Two earlier case reports in 2005 were also referenced. To this count should be added two additional case reports of hepatoxicity associated with Hydroxycut. An estimated 15% of the US population uses dietary supplements for weight loss, and Hydroxycut is the top selling product in this class and market, with roughly a million units sold per year. With such wide usage, these six cases may underestimate the true incidence of hepatoxicity by several degrees of magnitude."

22. Hepatotoxicity is chemical induced liver damage.

23. Despite the fact that Defendants knew or reasonably should have known of the dangers associated with its Hydroxycut products, Defendants did not issue any recall of its products prior to May 1, 2009.

24. Despite the fact that Defendants knew or reasonably should have known of the dangers associated with its Hydroxycut products, Defendants did not attempt to warn consumers of the risks prior to May 1, 2009.

25. Despite the fact that Defendants knew or reasonably should have known of the dangers associated with its Hydroxycut products, Defendants did not substantially alter its marketing efforts prior to May 1, 2009.

26. Prior to May 1, 2009, the United States Food and Drug Administration received at least 23 reports of serious health problems associated with Hydroxycut products ranging from jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplant. At least one death due to liver failure has been reported to the FDA. Other health problems reported include seizures, cardiovascular disorders, and rhabdomyolysis, a type of muscle damage that can lead to other serious health problems such as kidney failure.

27. On May 1, 2009, Defendants agreed with the FDA to voluntarily recall more than a dozen defective and dangerous Hydroxycut products.

28. Defendants' decision to recall the defective products, however, was downplayed in a press release from the Defendants in which they stated that the number of cases of adverse health consequences is relatively small, that their products are extensively tested, and that they disagreed with the FDA's assessment of the risk to consumers. (See Defendants' May 1, 2009 Press Release attached hereto as Exhibit B).

29. Despite the fact that Defendants knew of the dangers associated with its recalled products, Defendants did not make a reasonable effort to warn the public of the risks associated with Hydroxycut for products purchased by the public, but not yet consumed, prior to May 1, 2009.

JURISDICTION AND VENUE

30. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§1331 and 1332. Plaintiffs are citizens of Tennessee, and the Plaintiff Class is comprised of

citizens of Tennessee and other states, and the Defendants are corporate citizens of the state of Delaware and Ontario, Canada. The amount sought exceeds $75,000.00.

31. At all times material hereto, the Defendants were doing business in the State of Tennessee and all or part of the transactions which gave rise to this action took place in the State of Tennessee. Defendants did business in the State of Tennessee by marketing, delivering to, and selling their defective and dangerous products in the State of Tennessee through direct market sales and retail distribution channels located in the State.

32. Venue is proper in this District pursuant to 28 U.S.C. §1391 because the Defendants do business in this District and the misrepresentations, negligence, and other misdeeds by Defendants took place in this District.

CLASS ACTION ALLEGATIONS

33. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

34. This suit is brought as a Class Action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of a Class of:

> All natural persons, excluding the Defendants, its/their officers, directors, and employees and any judge who may be assigned to hear this controversy, who are residents of the United States and who purchased one the dangerous/defective products manufactured and/or distributed and/or marketed by Defendants that are subject to FDA recall through the trial of this cause.

35. Members of the Class are numerous. Plaintiffs do not, as yet, know the exact size of the Class. Based upon the popularity of the Defendants' products, as well as published media reports, Plaintiffs believe that there are several thousand or tens of thousands Class Members, and that the Class Members are geographically dispersed throughout the United States. Joinder

of all Members of the Class, therefore, is not practicable. However, the Members of the Class are readily identifiable from their proof of purchase of the defective and dangerous products of Defendants.

36. There are questions of law and fact common to the Class that predominate over any questions that may affect only individual Members of the Class, including, but not limited to:

a. Whether the conduct of Defendants violated T.C.A. § 53-1-101, *et seq.*;

b. Whether the conduct of Defendants violated common law;

c. Whether the conduct of Defendants constitutes fraud on consumers; and,

d. The type and measure of damages suffered by Plaintiffs and the Members of the Class.

37. Plaintiffs will fairly and adequately protect the interests of the Class in that Plaintiffs' claims are typical and representative of the claims of all Members of the Class, all of whom are victims of the Defendants' unfair and/or deceptive practices and dangerous/defective products.

38. There are no defenses of a unique nature that may be asserted against Plaintiffs individually, as distinguished from the other Members of the Class, and the relief sought is common to the Class. Plaintiffs purchased the Hydroxycut products subject to the recall, and do not have any interest that is in conflict with, or is antagonistic to, the interests of the Members of the Class, and have no conflict with any other Member of the Class. Plaintiffs have retained competent counsel experienced in class action litigation to represent them and the entire Class.

39. A Class Action is superior to other available methods for the fair and efficient adjudication of this controversy. In the absence of a Class Action, the Defendants will retain the

benefits of their wrongful and deceptive conduct. Prosecution as a Class Action will eliminate the possibility of repetitious litigation. The wrongs suffered and remedies sought by the representative Plaintiffs and the other Members of the Class are identical. The prosecution of separate actions by individual Members of the Class would create a risk of:

a. Inconsistent or varying adjudications for individual class members which would establish incompatible standards of conduct for the Defendant; and;

b. Adjudications for individual class members that would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or would substantially impair or impede their ability to protect their individual interests.

40. A certification of the Class would allow litigation of claims that, in view of the expense of litigation, may be insufficient in amount to support individual actions. The individual Class Members are unlikely to be aware of their rights and not in a position, by way of experience or financial means, to commence individual litigation against the Defendants.

41. At an early practicable time, Plaintiffs request that the court determine by order whether to certify the action as a class action and issue an order so certifying the class that defines the class and the class claims, issues, or defenses, and appoints class counsel under Federal Rule of Civil Procedure 23(g). Further, the court should order and direct appropriate, proper and reasonable notice to the class as well as defining the appropriate procedures for the conduct of this action.

42. As provided in Federal Rule of Civil Procedure Rule 23, in appointing class counsel to fairly and adequately represent the interests of the class, the court should consider: (a) the work counsel has done in identifying or investigating potential claims in the action; (b) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (c) counsel's knowledge of the applicable law; (d) the resources that

counsel will commit to representing the class; and (e) any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class.

GENERAL ALLEGATIONS

43. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

44. Defendants manufactured certain dangerous and defective weight loss and dietary supplement products that were recalled by the United States Food and Drug Administration on May 1, 2009 (a list of the dangerous and defective products is attached hereto as Exhibit C).

45. Defendants marketed those dangerous and defective products to Plaintiffs through television, print, and Internet advertising.

46. Defendants sold those dangerous and defective products to Plaintiffs through retail chain outlets including, but not limited to, Wal-Mart and Walgreens stores, at prices of at least $20.00 per product.

47. Defendants marketed the products in question as safe and healthy for the persons buying and using them.

48. In reality, those products have been shown to have serious adverse health effects, including, but not limited to, liver damage.

49. The Defendants knew, or in the very least should have known, that its products posed a serious health risk to the very consumers they targeted with their marketing efforts.

INDIVIDUAL ALLEGATIONS

50. Plaintiffs incorporates by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

51. The Plaintiff Patricia Akins purchased Hydroxycut Hardcore Liquid Caplets and Hydroxycut 24 from a retail General Nutrition Center store. The Plaintiff Monique Baker purchased Hydroxycut Regular Rapid Release Caplets from a retail Krogers grocery store after seeing television advertising for Hydroxycut. The Plaintiff Ruth Epperson purchased Hydroxycut Caffeine-Free Rapid Release Caplets from a retail Walgreens store after seeing television advertising for Hydroxycut. The Plaintiff Cory Flenoy purchased Caffeine-Free Rapid Release Caplets from a retail Walgreens store after seeing television advertising for Hydroxycut. The Plaintiff Nakitta Gamble purchased Hydroxycut Regular Rapid Release Caplets from a retail Krogers grocery store. The Plaintiff James McClinton purchased Hydroxycut Regular Rapid Release Caplets from a retail Wal-Mart store after seeing television advertising for Hydroxycut.

52. The Plaintiff Patricia Akins has spent an estimated $5,000.00 on the recalled products. The Plaintiff Monique Baker has spent an estimated $42.00 on the recalled products. The Plaintiff Ruth Epperson has spent an estimated $70.00 on the recalled products. The Plaintiff Cory Flenoy has spent an estimated $400.00 on the recalled products. The Plaintiff Nakitta Gamble has spent an estimated $20.00 on the recalled products. The Plaintiff James McClinton has spent an estimated $1,800.00 on the recalled products.

53. The Plaintiff Patricia Akins has suffered stomach and abdominal pain and recurring headaches as a result of using the recalled products. The Plaintiff Monique Baker has suffered nausea, vomiting, excessive fatigue, excessive weakness, stomach and abdominal pain, and loss of appetite as a result of using the recalled products. The Plaintiff Ruther Epperson has suffered brown urine, light colored stools, and stomach and abdominal pain as a result of using

the recalled products. The Plaintiff Cory Flenoy has suffered nausea, vomiting, excessive fatigue, excessive weakness, stomach and abdominal pain, and anxiety attacks requiring the care of a psychiatrist as a result of using the recalled products. The Plaintiff Nakitta Gamble has suffered stomach and abdominal pains as a result of using the recalled products. The Plaintiff James McClinton has suffered brown urine, nausea, vomiting, stomach and abdominal pain, loss of appetite, and blood in his urine as a result of using the recalled products.

COUNT I: STRICT LIABILITY—FAILURE TO WARN AND INSTRUCT

54. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

55. Defendants engaged in the development, testing, manufacturing, marketing and sales of those certain dangerous and defective products previously identified herein. Defendants designed, manufactured, assembled, marketed the products to national retail chain stores, knowing that consumers would purchase and consume the dangerous products.

56. Defendants distributed and sold the dangerous and defective products in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The products were expected to and did reach Plaintiffs without substantial change or adjustment in their condition as manufactured and sold by Defendants.

57. The dangerous and defective products designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the products.

Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of their weight loss products.

58. The dangerous and defective products were purchased and used in the manner for which they were intended, that is for oral consumption with the hope that such consumption would result in weight loss. This use has resulted in injury to Plaintiffs.

59. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the dangerous products in question created a high risk of bodily injury and serious harm. Despite this knowledge, Defendants failed to add to or strengthen the warning regarding adverse events occurring with the defective products. Defendants also failed to add to or strengthen the instructions or label warnings for safe use of the products. Defendants' conduct violated the common law duty to warn and instruct.

60. Defendants' failure to warn and instruct regarding the frequency and severity of adverse events occurring with the Defendants' products was both a but-for and proximate cause of Plaintiffs' injuries.

61. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT II: POST RECALL STRICT LIABILITY—FAILURE TO WARN AND INSTRUCT

62. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

63. Defendants engaged in the development, testing, manufacturing, marketing and sales of those certain dangerous and defective products previously identified herein. Defendants designed, manufactured, assembled, marketed the products to national retail chain stores, knowing that consumers would purchase and consume the dangerous products.

64. Defendants distributed and sold the dangerous and defective products in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The products were expected to and did reach Plaintiffs without substantial change or adjustment in their condition as manufactured and sold by Defendants.

65. The dangerous and defective products designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the products. Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of their weight loss products.

66. The dangerous and defective products were purchased and used in the manner for which they were intended, that is for oral consumption with the hope that such consumption would result in weight loss. This use has resulted in injury to Plaintiffs.

67. On May 1, 2009, the FDA issued a Class I Recall of the products that are the subject of this lawsuit. Class I Recalls are the most serious type of product recalls and involve situations in which there is a reasonable probability that the use of the product will cause serious injury or death.

68. Concurrent with the FDA recall, Defendants issued a press release de-emphasizing the risk to consumers. (See the press release attached as Exhibit B).

69. Defendants know or reasonably should know, that many of the dangerous products subject to the recall are already in the possession of consumers, including the Plaintiffs.

70. Defendants made no reasonable effort to warn the consumers of its dangerous products, including Plaintiffs, that the products already in their possession posed a significant health risk.

71. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT III: STRICT LIABILITY—DESIGN DEFECT

72. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

73. The recalled products that are the subject of this lawsuit are defectively designed because the foreseeable risks of adverse health consequences outweigh the alleged weight loss benefits associated with the products.

74. The recalled products were defectively designed in that they had a propensity to cause serious adverse health consequences including, but not limited to, severe liver damage. Had the products been designed to achieve the desired effect without passing through and/or damaging the liver organ, the products would not have injured the Plaintiffs.

75. The recalled products were expected to and did reach the Plaintiffs without substantial change or adjustment.

76. Defendants acknowledge that they subjected the recalled products to extensive testing before selling the products to the consumer, including Plaintiffs. (See press release attached as Exhibit B).

77. As a result of that extensive testing, Defendants knew, or reasonably should have known, of deficiencies and defects in the design of the recalled products. Defendants also knew or reasonably should have known of the design defects and the risk of serious bodily injury that exceeded the benefits associated with the products.

78. Furthermore, the products and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect, especially for a product marketed as designed to improve health.

79. Defendants failed to advise the consumer, including Plaintiffs, of the risks inherent in the design of its products.

80. The recalled products are inherently dangerous for their intended use due to design defects. Defendants are therefore strictly liable.

81. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT IV: NEGLIGENCE

82. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

83. Defendants have a duty to provide a safely manufactured product, to warn and instruct regarding the risk and severity of adverse events occurring with the recalled products, to add or strengthen warnings and instructions, and to provide reasonable assurance with respect to the safety and effectiveness of the products. Defendants breached these duties.

84. Defendants also had a duty to use reasonable care in all aspects in the design and manufacture of the recalled products. Defendants knew, or reasonably should have known, of defects in the designs of the recalled products that would severely injure the human body. Defendants admit that their recalled products were subject to extensive testing prior to being sold to consumers. Upon information and belief, the design defects include, but are not limited to, the choice of ingredients in the products and the impact of the recalled products on the human liver. Defendants breached this duty by designing the products, failing to properly test the products before selling them to the consumer, and failing to warn consumers of any design risks revealed by such testing.

85. Defendants have a duty to provide reasonable assurances regarding the safety and effectiveness of the recalled products. Defendants breached this duty by failing to warn on the packaging of the recalled products of the risk of adverse health consequences to the human body and by failing to make a reasonable effort to notify consumers, including Plaintiffs, of the recall of the products after May 1, 2009.

86. Upon information and belief, Defendants were aware, or reasonably should have been aware, of information that reasonably suggested the recalled products had design defects and that such defects would likely contribute to or cause serious injury or death.

87. After May 1, 2009, Defendants were aware that the recalled products would likely contribute to or cause serious injury or death and Defendants failed to provide adequate warnings

to consumers, including Plaintiffs, that had purchased the recalled products prior to May 1, 2009, but had not yet consumed the products.

88. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT V: BREACH OF IMPLIED WARRANTY

89. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

90. Defendants impliedly warranted that their weight loss products and supplements, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use.

91. Defendants further impliedly warranted that their weight loss products and supplements, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were fit for the particular purposes for which they were sold.

92. Contrary to these implied warranties, the recalled products were defective, unmerchantable, and unfit for their ordinary use when sold, and unfit for the particular purpose for which they were sold.

93. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VI: BREACH OF EXPRESSED WARRANTY

94. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

95. Defendants expressly warranted to Plaintiffs by and through Defendants and/or their authorized agents, that the recalled products were safe, effective, fit and proper for their intended use.

96. Defendants warranted on the packaging of their recalled products that their supplements included "clinically proven ingredients".

97. In deciding to consume the recalled products, Plaintiffs relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the recalled products were not safe and were unfit for the uses for which they were intended.

98. Through sale of the recalled products, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

99. Defendants breached their warranty of the ordinary purpose for which goods such as the recalled products are used by continuing sales and marketing campaigns highlighting the safety and health benefits of its products, while it knew, or reasonably should have known, of the defects and increased risk of the products having adverse health consequences.

100. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VII: NEGLIGENT MISREPRESENTATION

101. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

102. At the time Defendants manufactured, marketed, sold and distributed the recalled products for use by Plaintiffs, Defendants knew or reasonably should have known of the use for which the recalled products were intended and the serious risks and dangers associated with the consumption of such products.

103. Defendants have a duty to accurately and truthfully represent the risks of the recalled products. Defendants breached that duty by misrepresenting and/or failing to communicate material facts regarding the safety and effectiveness of the recalled products which Defendants knew, or in the exercise due of diligence should have known. Defendants also failed to exercise reasonable care or competence in obtaining or communicating this information.

104. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VIII: INTENTIONAL MISREPRESENTATION

105. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

106. Defendants have a duty to provide accurate and complete information regarding the recalled products.

107. Defendants falsely and deceptively sought to create the image and impression that the recalled products were safe for human use and had no unacceptable side effects.

108. Defendants purposefully concealed, omitted, misstated, and downplayed the health hazards and risks associated with the use of the recalled products.

109. Following the May 1, 2009 product recall, Defendant has purposefully downplayed the health hazards and risks associated with the use of the recalled products despite obvious evidence to the contrary, effectively making this warning deceptive. (See Defendants' press release attached as Exhibit B).

110. Defendants misrepresented the nature and scope of the problems related to the recalled products including the severity of adverse health consequences. Upon information and belief, Defendants intentionally delayed the dissemination of any evidence of the increased likelihood of injury from the recalled products.

111. Defendants have a duty to accurately and truthfully represent the risks of the recalled products. Defendants possessed evidence demonstrating the adverse health consequences of the recalled products. Defendants breached that duty by intentionally misrepresenting material facts regarding the recalled products.

112. Defendants engaged in the acts and omissions described above with the intent that others would rely thereon.

113. Plaintiffs justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations and/or omissions. This reliance proximately caused the injuries as damages detailed herein.

114. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT IX: FRAUD

115. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

116. Defendants knowingly misrepresented material facts regarding the safety and effectiveness of the recalled products with the intent that the public rely on the representation. The public, including the Plaintiffs, justifiably relied on these representations and had no knowledge that Defendants in fact misrepresented or omitted the key information about the adverse health consequences of consuming the recalled products.

117. Defendants were under a duty to disclose to Plaintiffs and the public the defective nature of the recalled products, and had full access to material facts concerning the defective nature of the recalled products and the propensity of the recalled products to cause adverse health consequences, and hence, cause injuries to the persons who consumed the products. Defendants breached that duty by misrepresenting this information.

118. Defendants' misrepresentations, concealment, suppression and omissions were made knowingly or recklessly to induce the purchase and use of Defendants' recalled products. Plaintiffs reasonably relied upon the Defendants misrepresentations and omissions when agreeing to purchase and/or consume the recalled products.

119. Defendants knew that Plaintiffs had no way to determine that the Defendants' representations about the recalled products were false and misleading, and that they included material omissions.

120. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional

distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT X: CONSTRUCTIVE FRAUD

121. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

122. Defendants are in a unique position of knowledge concerning the safety and effectiveness of the recalled products, which knowledge is not possessed by Plaintiffs, and Defendants thereby hold a position of superiority over Plaintiffs.

123. Despite their unique knowledge regarding the defective nature of the recalled products, Defendants continue to misrepresent material facts concerning the defects and the adverse health consequences.

124. Upon information and belief, Defendants' misrepresentations are designed to induce Plaintiffs to purchase the recalled products. Plaintiffs have relied upon these representations.

125. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

126. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT XI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

127. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

128. Defendants carelessly and negligently manufactured, marketed and sold the recalled products to Plaintiffs, carelessly and negligently concealed the products' defects from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and usefulness of the products.

129. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase and have implanted a defective and dangerous products manufactured, sold and distributed by Defendants.

130. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT XII: LOSS OF CONSORTIUM

131. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

132. At all relevant times hereto, the Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Plaintiffs' injuries.

133. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment,

monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

134. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

135. For all Spouse Plaintiffs, Plaintiffs allege their marital relationships have been impaired and depreciated, and the marital association between husband and wife has been altered.

136. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

137. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

COUNT XIII: UNJUST ENRICHMENT

138. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

139. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the sale of their recalled products.

140. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs, as reasonable consumers, expected.

141. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT XIV: VIOLATIONS OF THE TENNESSEE FOOD, DRUG AND COSMETIC ACT

142. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

143. Defendants marketed to consumers, including Plaintiffs, those certain recalled products using promises of a safe and healthy product. Those claims in both print and broadcast advertising were false, as the recalled products have been proven to cause adverse health consequences in consumers.

144. Defendants violated Tennessee Code Annotated § 53-1-103(a)(5) of the Tennessee Food, Drug and Cosmetic Act by disseminating false and misleading advertisements for the recalled products.

145. Defendants placed labeling on the recalled products implying that the recalled products were safe for human consumption. Those labels were proven false and misleading as the recalled products have been proven to cause adverse health consequences to consumers.

146. Defendants violated Tennessee Code Annotated § 53-1-103(a)(1) of the Tennessee Food, Drug and Cosmetic Act by manufacturing, selling, and offering for sale a drug that is misbranded.

147. Defendants violated Tennessee Code Annotated § 53-1-113(a) of the Tennessee Food, Drug and Cosmetic Act by advertising its recalled products as safe for human consumption when, in fact, those products have been proven to cause adverse health consequences in consumers.

148. As a direct and proximate result of Defendants' violations of the Tennessee Food, Drug and Cosmetic Act, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT XV: NEGLIGENCE PER SE

149. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

150. As Plaintiffs allege *supra*, the Tennessee Food, Drug and Cosmetic Act places certain requirements on advertising and products labeling. That statute establishes a definitive standard of care when marketing drug products to the public at large.

151. Plaintiffs are within the class of persons the statute is designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

152. Defendants' actions breached the duties established by the Tennessee Food, Drug and Cosmetic Act. Additionally, Defendants' actions also breached their parallel common law duties to provide safe products, to warn and instruct regarding the possibility of adverse health consequences occurring with the recalled products, to add to or strengthen warnings and instructions, and to provide reasonable assurance with respect to the safety and effectiveness of their products. Defendants breached these duties.

153. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

WHEREFORE, the Plaintiffs, on behalf of themselves and all others similarly situated, pray that this Court:

1. Certify this case as a Class Action under Rule 23 of the Federal Rules of Civil Procedure;

2. Award the Plaintiffs and the other Members of the Class their actual economic and non-economic damages, in an amount to be determined at trial but in no event less than $75,000.00, for the wrongful and deceptive acts of the Defendant;

3. Award Plaintiffs and the Members of the Class the costs of suit, including discretionary costs pursuant to Rule 54 of the Federal Rules of Civil Procedure;

4. Award reasonable attorneys' fees under the common fund doctrine;

5. Award the Plaintiffs and the other Members of the Class pre-judgment and post-judgment interest;

6. Award the Plaintiffs and the other Members of the Class punitive damages;

7. Award such other and further relief as the Court deems just and proper under the circumstances; and

8. The disgorgement of profits.

A JURY IS RESPECTFULLY DEMANDED TO TRY THESE ISSUES

Respectfully submitted,

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